(daily) or 35 mg (weekly) between January 2001 and June 2002. The first prescription for one of these medications was considered the index prescription. Non-persistence was defined as a >30 days gap between two subsequent prescriptions. Compliance was measured using the medication possession ratio (MPR), with analyses conducted using both continuous and categorical definitions. Outcomes were compared between daily and weekly regimens. **RESULTS:** Of the 2905 new users identified based on a 6-month run-in, 31% had an index prescription for a daily regimen, 69% for a weekly regimen. After six months, 46.7% of women on the weekly regimen and 41.9% on the daily regimen persisted with their therapies. At 12 months, the percentages were 27.7% and 18.9%. Longer persistence was thus observed for once-weekly users (median: 146 vs. 120 days), but the differences were not significant. At 12 months, weekly users had a significantly higher MPR than daily users (53.7% vs. 46.9%, P = 0.0022). Similarly, the proportion of highly compliant patients (≥80%) was 23% for the daily versus 32% for the weekly regimen (P = 0.0025). A larger proportion of patients starting on a weekly regimen remained on the same treatment over time (98% vs. 42% for those still treated at 12 months). An average of 1.15 switches per patient was observed. **CONCLUSIONS:** Although higher rates of compliance are observed for the weekly compared to the daily regimen, compliance and persistence rates for both regimens are suboptimal, and the social and economic implications of such behavior are known to be substantial.

HP6

EFFECT OF CO-PAYMENT ON COMPLIANCE TO STATINS AFTER CORONARY HEART DISEASE HOSPITALIZATION

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OBJECTIVES: To examine effect of co-payment on compliance among patients who initiated statins within 6-months of hospital discharge for coronary heart disease (CHD). **METHODS:** Medstat Marketscan Commercial and Medicare 1999–2003 databases containing inpatient admission, outpatient and pharmacy claims were utilized for this study. The first fill date of a prescription for statins within 6 month following CHD hospitalization was identified as the index date. The study sample consisted of adults who had no statin use during the year prior to the CHD hospitalization and had at least 12 months of follow-up after the index date. Medication possession ratio (MPR) was calculated as the ratio of total days supply for statins to total days during 12-month follow-up. Being compliant to statins was defined as having a MPR of 80% or greater. Effect of co-payment on compliance to statins was examined by a multiple logistic regression, controlling for age, gender, region, year of the index date, type of CHD, concomitant co-morbidity and concomitant use of other medications. **RESULTS:** In total, 5548 patients met the inclusion criteria and were included in the analysis. In total, 3404 (61.36%) had a MPR of 80% or over and were considered compliant to statins. Compared with those who had a co-payment of $10 or lower, patients with a co-payment over $20 were significantly less likely to be compliant to statins (OR, 0.46; 95% CI, 0.40–0.54). Other factors significantly associated with compliance in the model were age, gender, region, hyperlipidemia, depression, concomitant use of non-statin lipid lowering drugs and beta-blockers, and type of CHD. **CONCLUSIONS:** High co-payment (>$20) appears to be a significant barrier to compliance to statins, even after adjusting for demographic and clinical variables.

HP7

ADHERENCE TO IMMUNOSUPPRESSIVE THERAPY IN PRIVATE PAYER TRANSPLANT RECIPIENTS

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OBJECTIVE: Poor patient outcomes associated with low levels of adherence to medication have been previously reported in several chronic conditions. In transplantation, inadequate immunosuppression (IS) can lead to rejection and graft loss as well as increased healthcare costs. We evaluated patient and regimen characteristics associated with IS adherence in a private payer transplant population. **METHODS:** U.S. commercial claims data for de novo kidney, heart, liver, lung, pancreas and kidney-pancreas recipients transplanted 1995–2003 were linked to data from the Organ Procurement Transplant Network, a national transplant registry. All patients had ≥1 IS refill and were followed up to 1-year post-transplant. Patients who switched between study drugs were excluded. Medication adherence was measured by the medication possession ratio (MPR) i.e. ratio of number of therapy days supplied to number of follow-up days. The Kaplan-Meier product-limit method was used to estimate time to non-adherence. Adherence was defined as having a MPR ≥ 90% and was modeled using multivariate logistic regression. **RESULTS:** In total, 349 transplant recipients met study criteria. Mean adherence to index IS therapy was 84% (MPR = 0.84). Mean time to non-adherence was 8.4 months. Older age (OR = 1.03, p = 0.0005) and higher number of primary care visits (OR = 1.02, p = 0.03) were associated with higher odds of adherence. Hispanic ethnicity (OR = 0.34, p = 0.004), more co-morbidities (OR = 0.90, p = 0.078), less than college education (OR = 0.66, p = 0.07), or a greater number of other prescription medications (OR = 0.95, p = 0.03) were associated with a lower likelihood of adherence. Copay and gender were not significantly associated with adherence. **CONCLUSIONS:** The mean level of adherence to immunosuppressive therapy was in congruence with previous findings for other chronic medications. Medication refill adherence was associated with age, race, co-morbidity index, education status, primary care visits and number of medications taken. Drug copay did not impact adherence to immunosuppression therapy in this transplant population.

HP8

PATIENT CHARACTERICS, GLYCEMIC CONTROL, AND THE USE OF ANTIDIABETIC AGENTS AMONG INDIVIDUALS DIAGNOSED WITH TYPE-2 DIABETES: EVIDENCE FROM THE UK

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OBJECTIVES: Glycosylated hemoglobin (HbA1c) is a well-established measure of glycemic control and evidence shows that maintaining an acceptable HbA1c level may be associated with lower rates of diabetic complications. Many countries have established specific HBa1c target values indicative of good glycemic control for patients with type-2 diabetes. This study examined the characteristics of patients with type-2 diabetes and investigated whether patients met the National Institute for Clinical Excellence (NICE) recommended target. **METHODS:** Data were obtained from the UK Mediplus Database. Patients identified as having type-2 diabetes between January 1, 2004 and June 30, 2004 was included in the analysis. Co-morbidities and complications were also examined. Use of antidiabetic medication between April 1, 2004 and June 30, 2004 was reviewed. A subset of the patients who received an HbA1c test was examined, as

was their use of antidiabetic medications in the 90 days prior to their HbA1c test. All results are descriptive in nature. **RESULTS:** A majority of the patient population was male in their mid-60. Hypertension (51%) and ischemic heart disease (19%) were commonly diagnosed co-morbidities. Of patients with type-2 diabetes, 30% received no antidiabetic medications, 41% were treated with a single antidiabetic agent (e.g., metformin, sulfonylurea), while the remaining patients received combination therapy. Over half of the patients who received some antidiabetic medication had an HbA1c that did not meet the NICE recommendation of 7.5% or less. Interestingly, more than 70% of the patients who received either insulin alone or in combination with oral antidiabetic medications (s) had HbA1c values greater than 7.5%. **CONCLUSIONS:** Despite recent important advances in pharmacotherapy for type-2 diabetes, glycemic control remains suboptimal for a large percentage of patients in the UK. In order to adhere to NICE recommendations, health care professionals may wish to consider further additive or alternative treatment options.

Health Related Quality of Life Based Patient Reported Outcomes: Session 2

QL5

CLINICAL RESPONSES TO TREATMENT AND CHANGES IN THE DERMATOLOGY LIFE QUALITY INDEX (DLQI) IN MODERATE TO SEVERE PLAQUE PSORIASIS PATIENTS TREATED WITH ADALIMUMAB

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OBJECTIVE: The link between clinical responses to treatment and changes in the Dermatology Life Quality Index (DLQI) has not been established in moderate to severe plaque psoriasis. The objective of this study was to determine changes in DLQI total score that correlate with clinical improvement in this patient group treated with adalimumab. **METHODS:** A randomized, double-blind, placebo-controlled, multi-center clinical trial for the treatment of moderate to severe plaque psoriasis with adalimumab was conducted. Patients (n = 147) were randomized to adalimumab 40 mg every other week (eow), adalimumab 40 mg weekly, or placebo, and were followed for up to 12 weeks. The correlation between changes in the DLQI total score and clinical assessment of psoriasis severity, using the Psoriasis Area and Severity Index (PASI), was evaluated. To determine a minimum clinically important difference (MCID) for DLQI total score, a change of between 25% and 49% in the PASI score was used. Three standard distributional methods were used to determine the MCID for DLQI total score. **RESULTS:** The MCID for DLQI total score ranged from 2.3 to 4.0. This represents changes in dermatologic functional limitations in patients who achieved at least a 25% improvement in PASI score. In patients who had achieved at least a 75% improvement in PASI score, mean improvement in DLQI total score was 10.8 points in patients randomized to adalimumab 40 mg eow, 11.5 points in those who had received adalimumab 40 mg weekly, and only 1.3 points in the placebo group. **CONCLUSION:** The MCID for DLQI total score established in this study was between 2.3 to 4.0. Given that adalimumab-treated patients experienced a mean change in DLQI of at least 10 points, improvement in dermatologic-related functional limitations with this treatment is likely above the MCID.

QL6

ADALIMUMAB REDUCES FATIGUE IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS (AS)—6-MONTH RESULTS OF A CANADIAN AS STUDY

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OBJECTIVES: Fatigue is a common, distressing symptom of ankylosing spondylitis (AS), a chronic inflammatory disease predominantly affecting the spine. This study evaluated whether adalimumab therapy reduced fatigue in patients with active AS. **METHODS:** A randomized, placebo-controlled, Phase III study of adalimumab was conducted in Canada with patients with active AS who had experienced an inadequate response to at least one NSAID or disease-modifying, antirheumatic drug (DMARD). Patients received either adalimumab 40 mg every other week or placebo for 24 weeks. Fatigue was assessed by the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), a widely used measure of fatigue in chronic illnesses, and the fatigue item of the BATH AS Disease Activity Index (BASDAI), a well-established instrument used in clinical studies to evaluate AS disease activity. FACIT-F scores range from 0–52, with higher scores representing less fatigue, and a >= 3-point change considered clinical meaningful. The BASDAI fatigue item ranges from 0–10, with lower scores reflecting less fatigue. **RESULTS:** A total of 82 patients (38 on adalimumab, 44 on placebo) were enrolled. At baseline, both arms had comparable demographics and disease characteristics. Baseline FACIT-F (adalimumab 24.4, placebo 23.6) and BASDAI fatigue (adalimumab 6.3, placebo 6.9,) were similar between arms. After 12 weeks, adalimumab patients had achieved statistically significantly greater improvement in FACIT-F than placebo patients (6.9 vs. 1.7, $p = 0.005$). In addition, patients on adalimumab had achieved statistically greater improvement in BASDAI fatigue vs. placebo (−1.7 vs. −0.5, $p = 0.006$). Even greater improvements were achieved at 24 weeks in adalimumab vs. placebo patients for both measures (FACIT-F, 7.8 vs. 2.6, $p = 0.013$, and BASDAI fatigue, −1.9 vs. −0.5, $p = 0.006$). Improvements in FACIT-F at both 12 and 24 weeks were clinical meaningful. **CONCLUSIONS:** These results indicate adalimumab treatment provides AS patients with statistically significant and clinically meaningful improvements in fatigue compared with placebo.

QL7

IMPACT OF LUTS ON QUALITY OF LIFE IN ITALIAN WOMEN

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OBJECTIVES: To describe the observed changes in quality of life and bother associated with LUTS at one year from baseline assessment in a sample of Italian women. **METHODS:** The FLOW study is a two-year observational investigation aimed at evaluating prevalence, clinical progression and QoL impact of female LUTS. Women aged ≥ 18 years, not pregnant, with LUTS for ≥3 months and negative dipstick were consecutively enrolled in 39 Italian Urology Centres. Symptoms and QoL were assessed by: ICIQ-LF, W-IPSS and SF-36. Differences between the questionnaires' scores at baseline and follow-up visits were calculated to assess deterioration or improvement in QoL. Here we refer to